



Office for Human Research Protections  
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January 6, 2005

Antonio M. Gotto, Jr., M.D., D.Phil.  
Provost for Medical Affairs and  
Dean of the Medical College  
Joan and Sanford I. Weill College of Medicine  
of Cornell University  
1300 York Avenue, Room F105  
New York, NY 10021

Sheila Cohen Zimmet, R.N., J.D.  
Associate Dean for Research  
Joan and Sanford I. Weill College of Medicine  
of Cornell University  
1300 York Avenue, Box 5  
New York, NY 10021

**RE: Human Research Subject Protections Under Multiple Project Assurance M-1185  
and Federalwide Assurance FWA-93**

**Research Project: Cytokines and Extracellular Matrix in  
Bronchopulmonary Dysplasia (Protocol # 0199-520)**  
**Principal Investigators: Dr. Zubair Aghai, Dr. Harmut Hanauske-Abel, and  
Dr. Alfred Krauss**

Dear Dr. Gotto and Ms. Cohen Zimmet:

As part of its May 24, 2004 letter to the Weill Medical College of Cornell University (WMC), the Office for Human Research Protections (OHRP) made the following determinations regarding the above-referenced research:

- (1) OHRP found that subjects were enrolled into Protocol #0199-520 prior to IRB

**review and approval**, as required by Department of Health and Human Services (HHS) regulations at 45 CFR 46.103(b) and 109(a).

(2) OHRP found that WMC could provide no documentation of written consent for twenty subjects enrolled in Protocol #0199-520, as required by 45 CFR 46.117(a).

OHRP has been provided with additional information regarding the above-referenced research, which leads OHRP to find that the above determinations were based on incomplete information and that its determinations were incorrect. This additional information included copies of signed informed consent documents for subjects believed to be enrolled in the research. **After review of this additional material, OHRP believes that only two subjects were enrolled on Protocol #0199-520, while the additional subjects listed as enrolled by WMC were actually entered into Protocol #1196-561.**

OHRP appreciates the continued commitment of your institution to the protection of human research subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

Patrick J. McNeilly, Ph.D.  
Compliance Oversight Coordinator  
Division of Compliance Oversight

cc: Mr. Jeffrey Lehman, President, Cornell University  
Ms. Dorothy Hilpmann, IRB Administrator, WMC  
Dr. David Behrman, Chairperson, IRB WMC  
Dr. Alfred Krauss, WMC  
Dr. Harmut Hanauske-Abel, UMDNJ  
Commissioner, FDA  
Dr. David Lepay, FDA  
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Dr. Bernard Schwetz, OHRP  
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Ms. Shirley Hicks, OHRP  
Ms. Janice Walden, OHRP  
Ms. Patricia El-Hinnawy, OHRP  
Ms. Janet Fant, OHRP